

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

MELISSA ROSSERO and)	Civil Action No. 2:14-cv-01084-CRE
CHRISTOPHER ROSSERO,)	
)	Hon. Cynthia Reed Eddy
Plaintiffs,)	
)	
vs.)	PROTECTIVE ORDER OF
)	CONFIDENTIALITY
ELI LILLY AND COMPANY,)	
)	
Defendant.)	
)	
)	
)	
)	
)	

WHEREAS, Defendant Eli Lilly and Company (“Lilly”) has moved for entry of a protective order pursuant to Federal Rule of Civil Procedure 26(c) to be applied to this matter;

WHEREAS, a protective order will expedite the flow of discovery material, facilitate the prompt resolution of disputes over confidentiality, and adequately protect confidential material;

NOW, THEREFORE, having found good cause, it is hereby ORDERED THAT:

1. The following definitions shall apply to this Stipulation and Protective Order of Confidentiality (“Order”):

a. “Party” shall mean a party to this action, any employee of such party and any counsel for such party.

b. “Documents” shall mean all “writings,” “recordings,” or “photographic” materials as described and defined in Rule 1001 of the Federal Rules of Evidence, including electronically stored information, whether produced

or created by a party or another person, and whether produced pursuant to Federal Rule of Civil Procedure 34, pursuant to a subpoena, by agreement or otherwise. This shall include, but not be restricted to, all interrogatory answers, responses to requests for production or for admission(s), deposition testimony and deposition exhibits.

c. “Confidential Information” shall mean all documents or portions thereof that the producing party reasonably and in good faith believes is subject to a protective order under Federal Rule of Civil Procedure 26(c)(1).

d. “Copies” shall mean any photocopies, reproductions, duplicates, extracts, summaries or descriptions of a document and/or Confidential Information.

e. “Producing party” shall mean any party or its counsel or any other person who produced the document(s) at issue.

f. “Designating party” shall mean any party or its counsel or any other person who has designated the document(s) at issue as confidential pursuant to paragraph 3, below.

g. “Receiving party” shall mean any party or its counsel or any other person to whom Confidential Information is furnished.

h. “Competitor of Lilly” means any manufacturer, developer, or seller of drugs other than Lilly or any person who, upon reasonable and good faith inquiry, could be determined to be an employee of any manufacturer or seller of drugs other than Lilly.

i. “Final conclusion of this litigation” shall mean the date fifteen (15) days following:

- (1) the Court’s entry of a stipulated dismissal, or
- (2) the Court’s entry of a voluntary dismissal, or

(3) the entry of a final, non-appealable order disposing of the case.

2. If Plaintiffs receive Lilly documents that are not publicly available from any source other than Lilly that, upon reasonable and good faith inquiry, could be determined to be documents authored or created by Lilly, Plaintiffs will treat such documents as confidential under the terms of this Protective Order. In the event Plaintiffs produce to Lilly pursuant to Rule 34 of the Federal Rules of Civil Procedure any documents falling within this paragraph, Lilly shall have thirty (30) days to designate said documents as confidential pursuant to paragraph 3. If Plaintiffs wish to challenge the confidentiality of such a document, Plaintiffs shall notify Lilly in writing within 90 days of receipt of said documents and append a copy of the document at issue. Lilly will have 30 days to provide a written response to Plaintiffs' challenge and, if the parties reach an impasse following a good faith effort to resolve the dispute, Plaintiffs may bring a motion with the Court at any time thereafter.

3. Any party shall have the right to designate any document the party believes in good faith contains Confidential Information in that party's custody or control and that are not publicly available, or any portion of any document the party believes in good faith contains Confidential Information, as "confidential" pursuant to the following procedures:

a. Subject to paragraph 3(c), below, designation of documents as confidential shall be made:

(1) in the case of documents in hardcopy form or in a modifiable electronic format, by affixing the following legend to each page of the document, or portion thereof, that is deemed by the producing party as confidential in such a way so as not to obscure any part of the text or content:

CONFIDENTIAL — SUBJECT TO A PROTECTIVE ORDER

(2) in the case of electronically stored documents (other than documents in a modifiable electronic format), by noting in the meta data or on the image for each document that the document is **CONFIDENTIAL — SUBJECT TO A PROTECTIVE ORDER**. The following shall appear on any cover letter referring to electronically stored documents and, to the extent possible, to the device (i.e. disc, hard drive, etc.) on which the documents are electronically stored:

CONFIDENTIAL — SUBJECT TO A PROTECTIVE ORDER
ROSSERO V. ELI LILLY AND CO., CIV. NO. 14-1084
IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

In the event electronically stored documents designated as confidential are produced in a native format, whenever the party to whom such documents are produced reduces such material to hardcopy form, that party shall designate the hardcopy documents with the legend as provided in paragraph 3(a)(1), above.

b. Subject to paragraph 3(d), below, designation of documents as confidential will be made before or at the time of production or disclosure.

c. To the extent that any party has heretofore designated certain documents as confidential, it will not be required to re-designate the same with the full legend set out in paragraph 3(a), above.

d. The inadvertent failure to designate a document or any portion thereof as confidential does not alter or waive the protected and confidential nature of the document or portion thereof and does not remove it from the scope of this Order. The party discovering such inadvertent failure to designate a document or portion thereof as confidential shall, within fifteen (15) days of such discovery, notify counsel for the receiving party in writing that the document or a specified portion thereof is to be designated as confidential under the terms of this Order.

e. Interrogatory answers; responses to requests for admission; responses to requests for production; deposition transcripts and exhibits; and pleadings, motions, affidavits, briefs or other papers filed with the Court that include quotes of, summaries of or copies of documents entitled to protection may be accorded status as Confidential Information but, to the extent feasible, shall be prepared in such a manner that the Confidential Information is bound separately from the portions of the document not entitled to protection.

4. The party designating information, documents, materials or items as Confidential Information bears the burden of establishing confidentiality. If a party in good faith disagrees with a confidential designation:

a. The party seeking to challenge any confidential designation will inform counsel for the designating party in writing of said disagreement within 90 days of receipt of the document.

b. Upon the designating party's receipt of written notification that there is a disagreement on a confidentiality designation, the producing party will have 30 days to provide a written response. The parties will confer in an effort to resolve the dispute without Court intervention.

c. If, after conferring, the parties cannot resolve the dispute despite good-faith efforts to do so, any party may move for a determination by the Court as to the appropriateness of the confidential designation. The proponent of confidentiality must show by a preponderance of the evidence that there is good cause for the document or portion thereof to have such protection.

d. Each document or portion thereof designated as confidential shall retain that designation and shall remain subject to the terms of this Order until such time, if ever, that the Court renders a decision that a particular document or portion thereof is not subject to this Order and any and all proceedings or interlocutory appeals challenging such decision have been concluded.

5. The producing party may redact the following information:
 - a. trade secret and confidential commercial information (pricing strategy; manufacturing or production information; and third party confidential sales, distribution, or prescription data);
 - b. names, addresses, Social Security numbers, tax identification numbers, e-mail addresses, telephone numbers, and any other information that would identify patients (other than plaintiffs);
 - c. names, addresses, Social Security numbers, tax identification numbers, e-mail addresses, telephone numbers and any other personal identifying information of health care providers, including but not limited to individuals, organizations, or facilities that furnish, bill, or are paid for healthcare services or supplies;
 - d. names, addresses, Social Security numbers, tax identification numbers, e-mail addresses, telephone numbers, and any other personal identifying information (not to include race, age, or gender) of individuals enrolled as subjects in clinical studies or identified in adverse event reports;
 - e. street addresses, Social Security numbers, tax identification numbers, dates of birth, home telephone numbers, and cellular telephone numbers of employees;
 - f. names, addresses, Social Security numbers, tax identification numbers, e-mail addresses, telephone numbers, and other personal identifying information of any clinical investigator involved in the reporting of an adverse event;
 - g. personal information not the specific focus of the request;
 - h. information necessary to comply with privacy rights that are guaranteed by the Pennsylvania Constitution, the United States Constitution, the Code of Federal Regulations, the Health Insurance Portability and Accountability

Act of 1996, and other applicable laws and regulations. *See, e.g.*, 21 C.F.R. §§ 20.111, 20.63, and 314.80; 45 C.F.R. §§ 160 and 164;

i. materials that contain information protected from disclosure by the attorney-client privilege, the work product doctrine, or other legal privilege protecting information from discovery in this lawsuit, which shall be identified in a privilege log that will be provided to the receiving party within ninety (90) days of production; and

j. those portions of documents that contain information relating to Defendant's products not at issue in this litigation.

k. On a prospective basis, the "other product" redaction contemplated by Paragraph 5(j) applied by Defendant after the date of this Order shall be subject to the guidelines set forth below.

(1) Redactions for other products shall be:

(a) Limited in scope to redactions of discrete and separate sections of documents whereby only information related to such other drugs is contained in such sections, and where the nature of the information discussed in such discrete sections is not related in context to the remaining responsive sections of the document, i.e., involving analysis, comparison, or otherwise necessary for full understanding of the responsive sections of the document; and

(b) Limited to restrictions imposed related to readability and contextual understanding, so that such redactions will not be made within paragraphs or sentences containing non-redactable information, and such that the readability and understanding of the context of the non-

redacted material is not impaired. Defendant will not redact tables of contents, cover pages, titles, section headers, or PowerPoint slide titles.

(2) Redactions for other products will not be applied to:

- (a) Final or draft versions of the Cymbalta US label/package insert, Core Data Sheet, Summary of Product Characteristics, and the label/package insert from any other country;
- (b) Information referencing studies or clinical trials that compare other products with Cymbalta;
- (c) References to other products in a Cymbalta clinical study protocol;
- (d) Reference sections of a Cymbalta clinical trial study report;
- (e) References to other drugs as exclusionary criteria for participating in a Cymbalta clinical trial or study;
- (f) References to other products in MedWatch forms or other documents concerning adverse event data for Cymbalta;
- (g) Other products that Defendant contemplated marketing or actually marketed as a combination product with Cymbalta;
- (h) Organizational charts or signature block references to other products; or
- (i) Information related to Prozac (fluoxetine) and discontinuation-emergent adverse events.

6. Redaction of material pursuant to paragraph 5 is subject to the following:

a. The party that has redacted Confidential Information shall, upon written or oral request, identify the nature of the information redacted in a specific document with sufficient detail to allow the requesting party to determine whether a challenge to the redacted information may be appropriate.

b. If the requesting party has a good-faith basis for challenging the redaction, that party shall inform counsel for the redacting party in writing of said challenge within 90 days of receipt of the document containing the redaction. The producing party will thereafter have 30 days to provide a written response.

c. If, after conferring, the parties cannot resolve the dispute despite good-faith efforts to do so, the party challenging the redaction may move for a ruling on the issue of whether certain information is entitled to redaction. The party that has redacted the information must show by a preponderance of the evidence that the redacted document or portion thereof is redacted pursuant to the relevant terms of paragraph 5, above, or is otherwise valid under applicable law. If the Court finds that said information should remain redacted, said information shall remain redacted and may not be used as evidence by either party at trial or at a hearing or be relied upon by either party's experts. If the Court finds that said information should not remain redacted, the redacting party shall provide an unredacted version of the document within fifteen (15) days of the Court's decision or, if the redacting party challenges such a decision, within fifteen (15) days of the conclusion of any and all proceedings or interlocutory appeals challenging the decision.

7. Counsel of record for the party receiving Confidential Information shall use reasonable efforts to limit the disclosure of Confidential Information, including any copies thereof, to the minimum number of persons necessary to

conduct this litigation. All copies of Confidential Information shall immediately be affixed with the confidentiality legend pursuant to the provisions of paragraph 3(a), above, if the legend does not already appear on the copy. All such copies shall be afforded the full protection of this Order.

8. Except as otherwise provided herein, or with the prior written consent of the party or other person originally designating a document as confidential, the persons to whom Confidential Information may be disclosed shall be as follows:

a. the Court, the Court's clerk(s), staff, employees, any Court-appointed Special or Discovery Master, any Court-appointed mediator, any mediator agreed to by the parties, and any court reporter or videographer transcribing or recording testimony, whether at a deposition, hearing, or trial;

b. any named party;

c. any attorney appearing as of record and any employee, agent, or representative of said attorney;

d. any person designated by the Court, in the interest of justice, upon such terms as the Court may deem proper;

e. any physician, nurse practitioner, medical professional, or other healthcare provider, and any employee or agent thereof, who prescribed Cymbalta for the Plaintiff or who provided care or treatment to Plaintiff during or following Plaintiff's cessation of Cymbalta;

f. Subject to the provisions of Paragraph 9, below, any of the following:

(1) any non-party witness appearing to testify at a deposition;

(2) any person with prior knowledge of the Confidential Information;

- (3) any consultant or expert retained for the purpose of assisting counsel in the lawsuit;
- (4) any employee or third-party contractor of counsel involved in organizing, filing, coding, converting, storing or retrieving data or in designing programs for handling documents or data connected with these actions, including the performance of such duties in relation to a computerized litigation support system; and
- (5) any employee or third-party contractor of counsel involved in trial preparation.

9. Before disclosing Confidential Information to any person listed in paragraph 8.f., above, the receiving party shall:

a. ensure that the individual to whom disclosure is to be made has been provided a copy of this Order and executed the Confidentiality Agreement attached hereto as Exhibit A, thereby agreeing to be bound by the terms of this Order concerning receipt and disclosure of Confidential Information; and

b. prepare a log providing the name, address, place of employment and employment capacity of each such person to whom disclosure of Confidential Information is made, together with a copy of the Confidentiality Agreement executed by that person. The receiving party shall maintain said log and the signed copies of the Confidential Agreement for five (5) years following the final conclusion of this litigation. The contents of said log will be privileged and will not be subject to disclosure absent an order by the Court.

10. Subject to the provisions of paragraphs 8 and 9, above, no disclosure of Confidential Information shall be made to any Competitor of Lilly. In the event any disclosure of Confidential Information to a Lilly Competitor is anticipated, the

disclosing party shall provide written notice no fewer than 15 days prior to any disclosure identifying the Competitor to whom Confidential Information will be disclosed and specifying the Bates number of the Confidential Information to be disclosed. Lilly shall have 15 days within which to object in writing to any proposed disclosure pursuant to this Paragraph.

11. Persons obtaining access to Confidential Information under this Order shall use the information for preparation and trial (including appeals and retrials) related to Cymbalta discontinuation litigation, and shall not use such information for any other purpose, including, but not limited to, business, governmental, commercial, or administrative or unrelated judicial proceedings.

12. Any party or person to whom Confidential Information has been furnished who receives from any non-party (including natural persons, corporations, partnerships, firms, governmental agencies, departments or bodies, boards or associations) a subpoena or other process that seeks production or disclosure of such Confidential Information shall promptly, and in any case by the close of the next business day, give telephonic notice or written notice by overnight delivery, e-mail or facsimile to counsel for the designating party. Both the telephonic notice and/or the written notice shall identify the documents sought and the return date of the subpoena or other process, and the written notice shall also include a copy of the subpoena or other process. The party or person receiving the subpoena shall also inform the person seeking the Confidential Information that such information is subject to this Order. No production or other disclosure of such information pursuant to the subpoena or other process shall occur before ten (10) days following the date on which notice is given, or the return date of the subpoena, whichever is earlier.

13. The parties shall maintain privilege logs pursuant to Federal Rule of Civil Procedure 26(b)(5). A privilege log shall be provided within 90 days after

each production of documents by a party except that a receiving party shall be permitted to request from the producing party that a privilege log for a particular production be provided within a shorter time period if the receiving party has a good faith basis for such a request in connection with a scheduled deposition.

a. No party is required to list on a privilege log any communications regarding the claims and defenses in these proceedings exclusively between a party and its in-house counsel, outside counsel, an agent of outside counsel other than the party, any non-testifying experts, and, with respect to information protected by Fed. R. Civ. P. 26(b)(4), testifying experts.

b. No party is required to list on a privilege log any privileged materials or work product created after November 1, 2012, by its in-house counsel, outside counsel, an agent of outside counsel other than the party, any non-testifying experts, and, with respect to information protected by Fed. R. Civ. P. 26(b)(4), testifying experts.

c. If a producing party identifies portions of discoverable information that are privileged and redacts such portions of the discoverable information on that basis, the producing party does not need to log the fact of redaction so long as, for e-mails, the bibliographic information (i.e., to, from, cc, bcc, date/time) is not redacted; and, for non-email documents, the redaction is noted on the face of the document.

d. A party's privilege log only needs to provide objective metadata (to the extent it is reasonably available and does not reflect privileged or protected information) and an indication of the privilege or protection being asserted.

e. If a party receiving a privilege log has a good-faith basis for challenging a producing party's privilege determination, the receiving party shall inform counsel for the producing party in writing of said challenge within 90 days

of receiving the privilege log. The producing party will have 30 days to provide a written response.

f. If, after conferring, the parties cannot resolve the dispute despite good-faith efforts to do so, the party challenging a privilege determination may move for a ruling on the issue of privilege. The producing party must show by a preponderance of the evidence that the withheld document or portion thereof is privileged, as set forth in paragraph 6.i. If the Court finds that said information is privileged, said information shall remain withheld or redacted and may not be used as evidence by either party at trial or at a hearing or be relied upon by either party's experts. If the Court finds that said information is not privileged, the producing party shall provide an unredacted version of the document within fifteen (15) days of the Court's decision or, if the producing party challenges such a decision, within fifteen (15) days of the conclusion of any and all proceedings or interlocutory appeals challenging the decision.

14. Inadvertent production of documents subject to work-product immunity, the attorney-client privilege, or other legal privilege protecting information from discovery shall not constitute a waiver of the immunity or privilege. With respect to such inadvertently produced documents, the following procedures shall apply, and the parties agree that such procedures constitute reasonable and prompt steps to prevent disclosure and to rectify the error of disclosure, pursuant to the Federal Rules of Civil Procedure:

a. The party discovering the inadvertent production will contact the opposing party to apprise that party of such production promptly.

b. If no dispute exists as to the protected nature of the inadvertently produced documents, any party in possession of inadvertently produced documents ("party in possession") shall, within fifteen (15) days of receiving the notice of inadvertent production, destroy the inadvertently produced

documents along with any copies and notes or other work product reflecting the contents of such documents, including the deletion of all inadvertently produced documents from any litigation-support or other database. The party in possession of the inadvertently produced documents shall certify the destruction and deliver the certification to the producing party within the 15-day period. In the event that only portions of the inadvertently produced documents contain privileged subject matter, the producing party shall substitute redacted versions of the documents within ten (10) days of the certification of destruction of the inadvertently produced documents.

c. If the party in possession believes that the documents are not subject to the protections of work-product immunity, attorney-client privilege or other legal privilege protecting information from discovery, the party in possession shall within fifteen (15) days of sending or receiving the notice of inadvertent production, object to the producing party's claim of protection by notifying the producing party of the objection in writing and specifically identifying the produced documents to which the objection applies. Upon the producing party's receipt of written notification, the parties will confer in an effort to resolve the dispute without Court intervention. If the parties cannot resolve the dispute, any party can, within fifteen (15) days of reaching an impasse, contact the Court to seek an in camera review of the documents in question. The proponent of the privilege and/or immunity has the burden of proving by a preponderance of the evidence that the inadvertently produced documents are entitled to protection. If the Court determines that the inadvertently produced documents are entitled to work-product immunity, attorney-client privilege or other legal privilege protecting information from discovery, the party in possession shall, within fifteen (15) days of the Court's decision, comply with the provisions of paragraph 14(b), above.

d. Upon receipt of notice of inadvertent production pursuant to paragraph 14(a), above, and until the parties have resolved the issue pursuant to paragraph 14(b) or (c), no use shall be made of inadvertently produced documents during depositions or at trial, nor shall they be disclosed to anyone who did not previously have access to them.

e. The Parties agree that employing electronic keyword searching to identify and prevent disclosure of privileged material constitutes “reasonable steps to prevent disclosure” under Federal Rule of Evidence 502(b)(2). Pursuant to Federal Rule of Evidence 502(d) and (e), the production of any discovery material by any party, whether inadvertent or not, shall be without prejudice to any subsequent claim by the producing party that such discovery material is privileged or attorney-work product, and shall not be deemed a waiver of any such privilege or protection in either the litigation pending before the court, or any other federal or state proceeding.

15. Failure to assert work-product immunity, the attorney-client privilege and/or other legal privilege protecting information from discovery in this lawsuit as to one document shall not be deemed to constitute a waiver, in whole or in part, of any work product immunity and/or privilege protection as to any other document, even if the documents involve the same or similar subject matter.

16. A deponent may be shown and examined about Confidential Information during a deposition subject to the terms of paragraphs 8 and 9, above. Deponents shall not retain or copy portions of the transcript of their depositions that contain Confidential Information not provided by them or their counsel. While a deponent is being examined about any Confidential Information, persons to whom disclosure is not authorized under this Order shall not be present.

17. Parties and deponents may, within thirty (30) days after receiving a deposition transcript, designate pages of the transcript and/or deposition exhibits as

confidential. Confidential Information within the deposition transcript may be designated by underlining the portions of the pages that are confidential and marking such pages with the confidentiality legend pursuant to the provisions of paragraph 3(a), above. Until expiration of the 30-day period, the entire deposition will be treated as subject to protection against disclosure under this Order. If no party or deponent timely designates confidential information in a deposition, none of the transcript or its exhibits will be treated as confidential. If a timely designation is made, the confidential portions and exhibits shall be filed under seal, separate from the portions and exhibits not so designated and all copies of the confidential portions and exhibits shall be treated as Confidential Information pursuant to the terms of this Order. If any party in good faith disagrees with a confidential designation of any portion of a deposition transcript or of any deposition exhibit, the procedures of paragraph 4, above, will govern.

18. Subject to the Federal Rules of Civil Procedure, the Federal Rules of Evidence, and Local Rules of this Court, Confidential Information may be offered into evidence at trial or any court proceeding.

a. If a party wishes to use Confidential Information during a Court proceeding or hearing other than trial, the proponent of the evidence must give two (2) days' advance notice in writing to the designating party prior to offering the evidence. This provision does not apply to depositions.

b. If the proponent of the evidence wishes to use Confidential Information at trial, the proponent of the evidence must give timely written notice to the designating party prior to offering the evidence (e.g., provision of an exhibit list identifying the Confidential Information). Any party may move the Court for an order that the evidence be received in camera or under other conditions to prevent unnecessary disclosure. In such case, the Court will determine whether the

proffered evidence should continue to be treated as Confidential Information and, if so, what protection, if any, may be afforded to such information.

19. Use of Confidential Information in Court. The parties will use the following procedure, absent further Court Order, for submitting to the Court papers consisting of, containing, or attaching Confidential Information: Any party seeking to file Confidential Information in support of a motion or other matter pending before the Court must first notify the producing party of its intent to file Confidential Information and seek agreement to de-designate such information no fewer than 14 days prior to any such filing. Absent a written agreement to the contrary by the designating party, any Confidential Information of any type filed in support of a motion or other matter pending before the Court shall be filed under seal by first filing a motion with the Court pursuant to the Local Rules, and then filing such Confidential Information, together with the Order granting the motion to seal either through the Court's ECF system for filing documents under seal, or in the alternative, if the Court does not allow electronic filing of document under seal, the Confidential Information shall be filed in paper form in an envelope delivered to the clerk of the Court and marked with the title and caption of this Action, the title of each document being filed, and a statement substantially in the following form: Pursuant to the Order of the Court dated _____, this envelope containing the above-entitled documents filed by [the name of the party] is not to be opened nor the contents thereof displayed or revealed, except by the Court, or in accordance with an Order of the Court.

20. Nothing in this Order shall preclude a party from introducing into evidence at trial or hearing any Confidential Information that is admissible under the Federal Rules of Evidence.

21. Nothing in this Order shall prevent or otherwise restrict counsel from rendering advice to their clients in this lawsuit and, in the course thereof, relying

generally on examination of Confidential Information, provided that, in rendering such advice and otherwise communicating with a client, counsel shall not make specific disclosure of any Confidential Information except pursuant to the provisions of this Order. Counsel shall at all times keep secure all notes, abstractions, or other work product derived from or containing Confidential Information and shall be obligated to maintain the confidentiality of such work product, even after the documents designated as confidential have been returned or destroyed pursuant to paragraph 23, below.

22. The provisions of this Order shall not terminate at the final conclusion of this litigation. This Order shall remain in full force and effect in perpetuity unless modified, superseded or terminated by written consent of the parties or by order of the Court. Each person subject to this Order shall continue to be subject to the jurisdiction of the United States District Court for the Western District of Pennsylvania for the purpose of enforcement of the terms of this Order for as long as the Order remains in effect. The Court shall not be divested of the power to enforce the terms of this Order as to any persons subject to the Order by the final conclusion of this litigation or by the filing of a notice of appeal or other pleading that arguably has the effect of divesting this Court of jurisdiction of this matter generally.

23. Within thirty (60) days after the final conclusion of this litigation (including without limitation any appeals and after the time for filing all appellate proceedings has passed):

- a. Confidential Information and, subject to paragraph 23(b) and (c), below, all copies of same (other than exhibits of record) shall either:
 - (1) be returned to the producing party, or
 - (2) at the option of the producing party (if it retains at least one copy of the designated document), be destroyed.

All parties shall make certification of compliance with this paragraph and shall deliver the same to the producing party not more than sixty (60) days after the final conclusion of this litigation.

b. Unless otherwise ordered by the Court, counsel may retain: (1) copies of pleadings or other papers that have been filed with the Court that contain Confidential Information, including exhibits thereto; (2) work product containing Confidential Information; and (3) official transcripts and exhibits thereto. Any documents retained following the final conclusion of the litigation will be maintained confidential and subject to the contents of this protective order.

c. The receiving party shall make a reasonable effort to retrieve any Confidential Information from any non-party to whom such information has been given, and shall notify the producing party in writing of the failure to retrieve any such documents. This notice shall (1) specifically identify the Confidential Information not returned, (2) identify the person from whom the Confidential Information could not be retrieved, and (3) state the efforts made to retrieve such Confidential Information and the reasons these efforts were unsuccessful.

24. Nothing in this Order shall prevent any party or other person from seeking modification of this Order or from objecting to discovery that it believes to be otherwise improper. The parties shall be given notice and an opportunity to be heard before the Court on any matter that in any way modifies this Order or may result in a decision affecting the substance or effect of this Order.

25. Nothing herein shall prevent any party from disclosing any document that it has produced to any other person or shall otherwise restrict the use of such documents by the producing party. Such use and/or disclosure shall not be deemed to waive or otherwise modify the protection or confidentiality provided in this Order.

26. Any party may expressly waive in writing the applicability of any provision of this Order to any document or portion thereof that the party produces. Such waiver shall apply only to the document or portion thereof to which the applicability of the specified provision of this Order is expressly waived.

27. Any material violation of this Order by any party or person to whom Confidential Information is disclosed pursuant to the terms of the Order shall constitute a violation of a court order and be punishable as such.

28. **GOOD CAUSE:** Good cause exists to issue a protective order in this case because disclosure and discovery activity in this action are likely to involve production of confidential, proprietary, or private information that qualify for protection under Federal Rule of Civil Procedure 26(c). The types of information likely to be produced, include, but are not limited to: information on corporate organization; IND/NDA submissions and information relating to product development; communications with FDA and state regulatory agencies; marketing research, plans and summaries; sales representative information, records and communications; sales representative training materials; financial and business information and records; external consultant work product and communications; Standard Operating Procedures and manuals; and product safety information.

IT IS SO ORDERED.

Dated: _____

United States Magistrate Judge

EXHIBIT A

I, _____, do hereby acknowledge that I have received a copy of the “PROTECTIVE ORDER OF CONFIDENTIALITY” (the “Order”) that was entered in the above referenced case, with respect to the manner in which confidential discovery information disclosed or made available in the course of the above referenced proceeding is to be treated by me.

I state that: (1) I have read and understand the Order and I hereby represent, warrant and agree that I will abide by the Order; (2) I will use the information or documents disclosed to me in connection with the above referenced proceeding pursuant to the terms of the Order; (3) upon the final resolution of the above referenced proceeding, I will destroy or return all such information and documents to the person or persons from whom I have received them; and (4) I consent to personal jurisdiction in the United States District Court for the Western District of Pennsylvania in the event any party or other person seeks to enforce any claim that I have failed to abide by the terms of the Order.

Signature of Declarant

Signature of Counsel of Record